University of California, Los Angeles

CONSENT TO PARTICIPATE IN RESEARCH

A Study to Determine the Genetic potential to produce anti-oxidants in persons with cat, dust-mite, or hay fever allergies

You are asked to participate in a research study conducted by Dr. David Diaz-Sanchez and Dr. Andrew Saxon, M.D. from the Division of Clinical Immunology and Allergy at the University of California, Los Angeles. This study is sponsored by the National Institutes of Health (NIH). You have been asked to participate in this study because you are a normal subject or a person with allergic rhinitis (hay fever), and you will undergo the same testing procedures no matter which of these qualifying criteria you satisfy. Your participation in this study is entirely voluntary. You should read the information below, and ask questions about anything you do not understand, before deciding whether or not to participate.

PURPOSE OF THE STUDY

The goal of this study is to determine the mechanisms on how diesel exhaust particulate (DEP) affects allergies. It has been observed that pollution makes allergies worse, and that natural chemicals (antioxidants) may protect against allergic reactions.

PROCEDURES

If you volunteer to participate in this study, the following procedures will be done:

1) You will be screened for allergic sensitivity to cat, dust, or ragweed pollen antigens. This screening procedure will consist of a small area of skin on the subject's arm being cleaned with alcohol and dried. A small amount of each allergen extract will then be applied to the skin via a small plastic "brush." Adjoining areas will be tested in the same manner with a sample of sterile water and histamine solution. Test results will be interpreted approximately 15 minutes after the solutions are placed. This procedure is identical to routine allergy screening tests. You will have been instructed to avoid antihistamines for a 72 hour period prior to this test. The results of this test will determine what you are allergic to.

2) A cheek scrape will be performed by gently scraping the inside of the mouth around the cheek with a sterile tongue depressor. A cheek scrape is done to obtain cells so we can extract DNA to test the general ability of people to make natural defenses (antioxidants). The results of the DNA testing will not be made available to you.

POTENTIAL RISKS AND DISCOMFORTS

The risks in the allergy skin testing are simply those of a positive reaction, which is the equivalent of a mosquito bite at the site of positive testing i.e. redness and itching. These last generally no more than 30 minutes and do not progress to more serious reactions.
The risk in cheek scraping is minimal, and involves a very low chance and a small amount of bleeding. There is also a small possibility of bruising and soreness of the cheek following the scraping procedure. The procedures may involve risks that are currently unforeseeable.

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ANTICIPATED BENEFITS TO SUBJECTS

You will not benefit directly from your participation.

ANTICIPATED BENEFITS TO SOCIETY

The benefits to society are an increased understanding of how natural chemicals, or antioxidants may protect against allergic reactions.

ALTERNATIVES TO PARTICIPATION

The alternative to participation is not to participate.

PAYMENT FOR PARTICIPATION

There is no payment for participation. However, if you are positive for any type of allergic reaction to what we are testing, you may qualify for future studies in which there will be financial payments.

POSSIBLE COMMERCIAL PRODUCTS

All tissue and/or fluid samples are important to this research study. Your sample will be owned by the University of California or by a third party designated by the University (such as another university or a private company). If a commercial product is developed from this research project, the commercial product will be owned by the University of California or its designee. You will not profit financially from such a product.

SAMPLE REMAINING AT THE END OF THE STUDY

The procedures involved will use all of your sample, and there will be none remaining.

INFORMATION ABOUT YOUR SAMPLE

Please indicate by checking and initialing the category below what type of information you want to receive. It is your responsibility to let the investigator know if your address and/or telephone number changes. The contact information is in this informed consent form under "Identification of Investigators."

☐ _____General Information about what this study found (or conclusions of the study)

☐ _____You may also choose not to receive any information. Research is a long and complicated process. Obtaining general information from a project may take years. Even if there is general information from a project, there may not be personal information for every participant.

FINANCIAL OBLIGATION

Neither you nor your insurance company will be billed for your participation in this research study.

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EMERGENCY CARE AND COMPENSATION FOR INJURY

If you are injured as a direct result of research procedures not done primarily for your own benefit, you will receive treatment at no cost. The University of California does not provide any other form of compensation for injury.

PRIVACY AND CONFIDENTIALITY

The only people who will know that you are a research subject are members of the research team and, if appropriate, your physicians and nurses. No information about you, or provided by you during the research, will be disclosed to others without your written permission, except:

- if necessary to protect your rights or welfare (for example, if you are injured and need emergency care); or
- if required by law.

Authorized representatives of the National Institute of Allergy and Infectious Diseases (NIAID) and the Public Health Services (PHS) may need to review records of individual subjects. As a result, they may see your name; but they are bound by rules of confidentiality not to reveal your identity to others.

Each tissue and fluid sample contains genetic information about your parents and ancestors such as the information contained in DNA, RNA, or protein. Your samples will be kept private and a code will be assigned to them, known only by the investigators. Codes will be kept locked in a drawer/cabinet to prevent access by unauthorized personnel.

GENETIC INFORMATION IN YOUR SAMPLE: POSSIBLE LIMITS TO INDIVIDUAL CONFIDENTIALITY

Every tissue or fluid sample contains genetic information. Recent studies have found normal and disease producing genetic variations among individuals. Such variations may permit identification of individual participants. Despite this possible limitation every precaution will be taken to maintain your confidentiality now and in the future.

We have learned from past research that we will not always be able to predict future research findings and new technologies. You should be aware that unforeseeable problems may arise from new developments. Possible problems include insurance or employment discrimination based on genetic information.

Sometimes genetic information suggestion different parentage is obtained during research. We do not plan to report such findings to participants.

Within the limits imposed by technology and the law, every effort will be made to maintain the privacy of your genetic information.

PARTICIPATION AND WITHDRAWAL

Your participation in this research is VOLUNTARY. If you choose not to participate, that will not affect your relationship with UCLA (or UCLA Medical Center), or your right to health care or other services to which you are otherwise entitled. If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without prejudice to your future care at UCLA.

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WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR

The investigator may withdraw you from participating in this research if circumstances arise which warrant doing so. The investigator, Dr. David Diaz-Sanchez, will make the decision and let you know if it is not possible for you to continue. The decision may be made either to protect your health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate.

NEW FINDINGS

During the course of the study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study will be re-obtained.

IDENTIFICATION OF INVESTIGATORS

In the event of a research related injury or if you experience an adverse reaction, please immediately contact one of the investigators listed below. If you have any questions about the research, please feel free to contact Dr. David Diaz-Sanchez at (310)825-9376, or (818)413-4647 24 hours/day, or Dr. Andrew Saxon, M.D. at (310)206-8050.

RIGHTS OF RESEARCH SUBJECTS

You may withdraw your consent at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding your rights as a research subject, you may contact the Office for Protection of Research Subjects, 2107 Ueberroth Building, UCLA, Box 951694, Los Angeles, CA 90095-1694, (310) 825-8714.

SIGNATURE OF RESEARCH SUBJECT

I have read (or someone has read to me) the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given a copy of this form, as well as a copy of the Subject's Bill of Rights.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBES.

Name of Subject

Signature of Subj

Date

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SIGNATURE OF INVESTIGATOR

I have explained the research to the subject and answered all of his/her questions. I believe that he/she understands the information described in this document and freely consents to participate.

Name of Investigator

Signature of Investigator

Date (must be the same as subject's)

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